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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,692	07/15/2004	Richard Smith-Carliss	END041182PCTUS	4419

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EXAMINER	
HUYNH, CARLIC K	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
07/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,692	SMITH-CARLISS ET AL.	
	Examiner	Art Unit	
	Carlic K. Huynh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *1-22,27,31 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-26 and 28-30* is/are rejected.

7)☒ Claim(s) *23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 July 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :07 September 2004 and 18 October 2004.

DETAILED ACTION

Status of the Claims

1. Claims 1-32 are pending in the application, with claims 1-12 having been withdrawn from consideration, in response to the restriction requirement submitted on April 30, 2007. Accordingly, claims 13-32 are being examined on the merits herein.

Election/Restrictions

2. Applicant's election without traverse of the claims of Group III, namely claims 13-32, in the reply filed on May 31, 2007 is acknowledged.

Claims 1-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on May 31, 2007.

3. Applicant's election of the species of (1) a compound of Formula II wherein $R^1 = R^5 =$ phenyl, $R^2 =$ ethyl, and $R^3 = R^4 =$ methyl and (2) HCl as the pharmaceutically acceptable salt, in the reply filed on May 31, 2007 is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the election of species requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 13-22, 27, and 31-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Namely, the compound of formula II in claims 13-22 and 27 are not $R^1 = R^5 =$ phenyl, $R^2 =$ ethyl, and $R^3 = R^4 =$ methyl and thus have been withdrawn. HCl as the

pharmaceutically acceptable salt is an inorganic acid addition salt, which is not the organic acid additional salts and salts with acidic amino acids as recited in claims 31 and 32, and thus claims 31 and 32 have been withdrawn. Election was made without traverse in the reply filed on May 31, 2007.

Accordingly, claims 23-26 and 28-30 are being examined on the merits herein.

The election/restriction requirement is deemed proper and is made FINAL.

Claims 23-26 and 28-30 are directed to a compound and thus intended use is not given any patentable weight. The claims have been examined insofar as to be read on the elected invention and species.

Priority

This application is a continuation of PCT/US02/27936, filed August 29, 2002, which claims benefit of priority to US provisional application serial no. 60/315,530 filed on August 29, 2001.

Information Disclosure Statement

The Information Disclosure Statements submitted on September 7, 2004 and October 18, 2004 are acknowledged.

Claim Objections

4. Claim 23 is objected to because of the following informalities: typographical errors. "anlgesia" is spelled incorrectly in the instant claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 23-26 and 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The nitrogen in the compound of Formula (II) should be presented with a positive charge since the nitrogen is quadvalent and the compound itself is a pharmaceutically acceptable salt form thereof.

6. Claims 23-26 and 28-30 recite the limitation "said amount is sufficient to induce anlgesia and/or deter abuse of abusive substances" in claim 23. There is insufficient antecedent basis for this limitation in the claim. The claim(s) itself do not elaborate on what "amount is sufficient to".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 23-26 and 28-30 are rejected under 35 U.S.C. 103(a) as obvious over Angelo et al. (Journal of Chromatography B, 1999, Vol. 724, pp. 35-40).

Angelo et al. teaches the main metabolite of methadone, 2-ethylidene-1,5-dimethyl-3,3-diphenyl-pyrrolidiene (EDDP) (p. 35, Introduction). The metabolite was detected in human urine of those who have taken methadone (abstract). The *rac*-methadone hydrochloride was supplied by a pharmacy in Bispebjerg Hospital (p. 36, Experimental, chemicals). EDDP was purchased as a perchlorate salt form and stock solutions were prepared in ethanol and water (p. 36, Experimental, chemicals).

Since the methadone was supplied by a hospital pharmacy, it would be obvious that the methadone from a hospital pharmacy was prepared as a pharmaceutical composition with pharmaceutically acceptable agents and excipients.

Since EDDP was purchased as a perchlorate salt form and stock solutions were prepared in ethanol and water, it would be obvious that the EDDP was prepared using pharmaceutically acceptable agents since ethanol and water are well known pharmaceutically acceptable agents.

However, regarding the species election of EDDP as a compound of formula (I) and the hydrochloride as an inorganic acid addition salt, it is noted EDDP was purchased as a perchlorate salt form. Perchlorate salt and hydrochloride salt are well known in the art as pharmaceutically acceptable salts. Thus, it would be obvious that EDDP may also be prepared as a hydrochloride salt form because both perchlorate salt and hydrochloride salt are pharmaceutically acceptable salt forms.

It is noted that this reference need not teach the intended use as a "pharmaceutical" but reasonably be considered as capable for the use.

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SHENGJUN WANG
PRIMARY EXAMINER

ckh